

COMPONENT E-C- progesterone and estradiol benzoate implant
Elanco US Inc.

Elanco™

Component™ E-C

(progesterone and estradiol benzoate implants)

Each implant consists of 100 mg progesterone USP and 10 mg estradiol benzoate

IMPLANTS FOR BEEF CALVES 45 DAYS OF AGE AND OLDER AND WEIGHING UP TO 400 LBS

20 dose Cartridge Belt

Use with a Component Implanter

DESCRIPTION:

Each cartridge belt holds 20 doses of Component E-C (progesterone and estradiol implant) Implants. Each dose of 5 pellets consists of 4 pellets containing a total of 100 mg progesterone USP and 10 mg estradiol benzoate.

INDICATIONS FOR USE:

For increased rate of weight gain in beef calves 45 days of age and older and weighing up to 400 lbs.

This implant is not approved for repeated implantation (reimplantation) with this or any other cattle ear implant as safety and effectiveness has not been evaluated.

Do not use in calves less than 45 days of age or veal calves because effectiveness and safety have not been evaluated.

Do not use in animals intended for subsequent breeding, or in dairy cows.

DIRECTIONS:

Administer 1 implant - the entire contents of one cartridge cell (5 pellets) - subcutaneously in the back of the middle third of the ear. Study and carefully follow at all times the "IMPLANTING INSTRUCTIONS" presented below, avoiding short cuts. Skin infection can be avoided by properly preparing implant site and implanter. During fly season use fly repellent on implant site. One designated team member should always do the implanting. Cleanliness of hands and instruments is important at all times.

Withdrawal Periods and Residue Warnings

No withdrawal period is required when used according to labeling.

Do not use in beef calves less than 45 days of age, dairy calves, and veal calves. Do not use in bull calves intended for reproduction. A withdrawal period has not been established for this product in pre-ruminating calves.

Do not use in dairy cows or in animals intended for subsequent breeding. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Implant pellets subcutaneously in ear only. Any other location is a violation of Federal law. Do not attempt salvage of implanted site for human or animal food.

USER SAFETY WARNINGS:

Not for use in humans. Keep out of reach of children.

ANIMAL SAFETY WARNINGS:

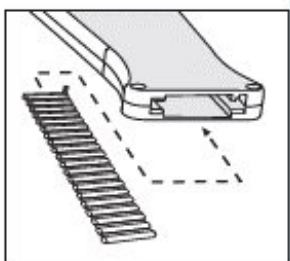
Bulling has occasionally been reported in implanted steers and heifers. Vaginal and rectal prolapse, udder development, ventral edema and elevated tailheads have occasionally been reported in heifers administered Component E-C implants.

Restricted Drug (California) - Use Only as Directed

IMPLANTING INSTRUCTIONS:

Loading the Implanter

Load the implanter following the instructions supplied with each implanter.



Restrain the Animal

Speed of implantation as well as safety of handlers is best achieved by restraining animal in a squeeze chute using head restraint.



Prepare the Implant Site

Scrub the back side of the ear (implant site) with a piece of clean absorbent cotton or brush which has been soaked with topical germicidal solution. Follow manufacturer's directions on germicide for correct strength and preparation of solution. Avoid getting disinfectant in animal's eyes.

Where to Implant

The full contents of one cartridge cell should be implanted beneath the skin on the back side of the middle one-third of the ear as illustrated in the drawing. The implant must not be closer to the head than the edge of the auricular cartilage ring farthest from the head. The location for insertion of the needle is a point toward the tip of the ear and at least a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear.



Insert the Needle

With one hand firmly grasp the ear. With the other hand insert needle point through the skin and ease forward on a lateral plane until the entire length of the needle is under the skin.



Implant the Pellets

After inserting the needle fully in the correct implant position, squeeze the trigger fully as the needle is withdrawn from the ear. This properly deposits the implant in the needle track. This procedure should prevent breakage or crushing of pellets if otherwise forced into contact with tough fibrous-tissue underlying the skin. The length and total contact area of a single dose are designed to permit absorption of the hormones after implantation to stimulate good weight gain. Broken or crushed pellets may lead to undesirable side effects such as bulling, rectal and vaginal prolapse, etc., as noted in the ANIMAL SAFETY WARNINGS.

STORAGE CONDITIONS:

Store at controlled room temperature 15° to 30°C (59° to 86°F) DO NOT refrigerate – avoid excessive heat and humidity. Discard open foil pouches.

Approved by FDA under NADA # 110-315

Manufactured by a non-sterilizing process.

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Distributed by Elanco US Inc., Greenfield, IN 46140, USA

June 2023

PA104037X

AH0792

Package/Label Principal Display Panel - Cartridge Belt Label

Elanco™

Component™ E-C

(progesterone and estradiol benzoate implants)

***BEEF CALVES 45 DAYS OF AGE AND OLDER
AND WEIGHING UP TO 400 LBS***

**One 20-Dose
Cartridge Belt**

Elanco™
Component™ E-C
 (progesterone and estradiol benzoate implants)

**BEEF CALVES 45 DAYS OF AGE AND OLDER
 AND WEIGHING UP TO 400 LBS**

Each implant consists of 100 mg progesterone USP and 10 mg estradiol benzoate
IMPLANTS FOR BEEF CALVES 45 DAYS OF AGE AND OLDER AND WEIGHING UP TO 400 LBS


DIRECTIONS: Administer 1 implant - the entire contents of one cartridge cell (5 pellets) - subcutaneously in the back of the middle third of the ear. See package insert for detailed instructions. Use a CAREFUL CLEAN TECHNIQUE. Never take short cuts at the expense of CLEANLINESS.

INDICATIONS FOR USE:
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Do not use in calves less than 45 days of age or veal calves because effectiveness and safety have not been evaluated. Do not use in animals intended for subsequent breeding, or in dairy cows.

Net Contents: One cartridge belt of 20 implants sealed in a sanitary foil pouch.

Manufactured by a non-sterilizing process.
 Approved by FDA under NADA # 110-315

TAKE TIME

One 20-Dose Cartridge Belt
 FL104037A

TEAR HERE (vertical arrows on right side)


3 0 4 0 3 7 (barcode numbers)

Withdrawal Periods and Residue Warnings
 No withdrawal period is required when used according to labeling.
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USER SAFETY WARNINGS: Not for use in humans. Keep out of reach of children.

ANIMAL SAFETY WARNINGS:
 Bulling has occasionally been reported in implanted steers and heifers. Vaginal and rectal prolapse, udder development, ventral edema and elevated tailheads have occasionally been reported in heifers administered Component E-C implants.
 Restricted Drug (California) - Use Only as Directed

STORAGE CONDITIONS: Store at controlled room temperature 15° to 30°C (59° to 86°F). DO NOT refrigerate - avoid excessive heat and humidity. Discard open foil pouches.

TAKE TIME

One 20-Dose Cartridge Belt
 FL104037A

EXP
LOT

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 Greenfield, IN 46140, USA

COMMENTS/QUESTIONS?
 For a copy of the Safety Data Sheet or to report side effects, contact Elanco US Inc. at 1-888-545-5973.
 For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>.

PURCHASE SEAL 20 IMPLANTS

 7 27804 00082 0

TEAR HERE (vertical arrows on left side)

4 0 4 0 3 7 (barcode numbers)

FL104037B AH0792

Package/Label Principal Display Panel - Carton Label

Elanco™

Component™ E-C

(progesterone and estradiol benzoate implants)

**BEEF CALVES 45 DAYS OF AGE AND OLDER
 AND WEIGHING UP TO 400 LBS**

100 IMPLANTS



COMPONENT E-C

progesterone and estradiol benzoate implant

Product Information

Product Type	OTC ANIMAL DRUG	Item Code (Source)	NDC:58198-0792
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PROGESTERONE (UNII: 4G7DS2Q64Y) (PROGESTERONE - UNII:4G7DS2Q64Y)	PROGESTERONE	100 mg
ESTRADIOL BENZOATE (UNII: 1S4CJB5ZGN) (ESTRADIOL - UNII:4TI98Z838E)	ESTRADIOL BENZOATE	10 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-0792-1	5 in 1 CARTON		
1		1 in 1 POUCH		

1	20 in 1 CARTRIDGE		
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Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA110315	01/02/2024	

Labeler - Elanco US Inc. (966985624)

Revised: 12/2023

Elanco US Inc.